Supreme Court, U.S.
FILED

03 862 DEC 11 2003

No.

In the Supreme Court of the United States

EXCEL CORPORATION,

Petitioner,

v.

ESTATE OF BRIANNA L. KRIEFALL, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin

PETITION FOR A WRIT OF CERTIORARI

RALPH A. WEBER
AMELIA L. MCCARTHY
SHAWN K. STEVENS
Reinhart Boerner Van Deuren S.C.
1000 North Water Street
P.O. Box 2965
Milwaukee, WI 53201
(414) 298-1000

ANDREW J. PINCUS
Counsel of Record
RICHARD B. KATSKEE
Mayer, Brown, Rowe & Maw LLP
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

Counsel for Petitioner

115 pp

QUESTION PRESENTED

The Federal Meat Inspection Act, 21 U.S.C. §§ 601-695, mandates comprehensive federal inspection of meat products, slaughtering facilities, and processing plants, and prohibits the shipment in commerce of meat that is "adulterated." 21 U.S.C. § 610(c). The Secretary of Agriculture has issued an interpretive rule stating that steaks, roasts, and other intact meats bearing the bacteria *E. coli* O157:H7 are not adulterated, because the bacteria are rendered harmless with ordinary cooking. The Wisconsin Court of Appeals held that it could not consider the Secretary's views in interpreting the statutory language, and concluded that such meat is adulterated within the meaning of the statute, invalidating the Secretary's administrative interpretation and subjecting meat processors to potential civil and criminal liability under state law for observing that federal standard.

The question presented is:

Whether the Federal Meat Inspection Act precludes the Secretary from issuing rules interpreting the key statutory term "adulterated," bars courts construing that term from giving any weight to the Secretary's interpretation, and therefore compels a construction of "adulterated" different from the Secretary's that subjects meat processors to conflicting standards.

PARTIES TO THE PROCEEDING

The petitioner is Excel Corporation.

The parties to the consolidated proceeding in the trial court were: as, plaintiffs, Estate of Brianna L. Kriefall, Douglas A. Kriefall, Connie J. Kriefall, Chad Kriefall, Ervin J. Lesak, Florence Lesak, Jeffrey Fortier, Judith Fortier, Tristan Fortier, Carly Fortier, Kevin McCormick, Sandy McCormick, and Kelsea McCormick; as "involuntary plaintiffs," Humana/Employers Health Insurance Company, Great West Life & Annuity Insurance, and Blue Cross Blue Shield United; as defendant and third-party plaintiff, Sizzler USA Franchise, Inc.; as defendants, Federal Insurance Co., E&B Management Co. Waukesha, Inc., Secura Insurance, SYSCO Services of Eastern Wisconsin, Excel Corporation, Fidelity and Guaranty Insurance Co., and American Home Assurance Co.; as defendants and third-party defendants, Lee M. Eschenbach, Steven C. Boysa, AAA Insurance Co., and BBB Insurance Co.; and, as third-party defendants, Cargill, Inc., and Excel Food Distribution, Inc.

RULE 29.6 STATEMENT

Petitioner Excel Corporation is a wholly-owned subsidiary of Cargill Incorporated, a privately-owned company.

TABLE OF CONTENTS

Page

QUESTION PRESENTED I

PARTIES TO THE PROCEEDING ii

RULE 29.6 STATEMENT iii

TABLE OF AUTHORITIES vi

OPINIONS BELOW 1

JURISDICTION 1

STATUTORY AND REGULATORY PROVISIONS INVOLVED 1

STATEMENT 1

A. The Federal Meat Inspection Act 3

1. *The Regulatory System* 3

2. *Preemption of State Law* 7

B. *E. Coli*-Related Illness And The Federal Response 8

C. Respondents' Lawsuit And The Trial Court's Grant Of Summary Judgment In Favor Of Excel 11

D. The Wisconsin Court Of Appeals' Decision 13

REASONS FOR GRANTING THE PETITION 15

I. THE WISCONSIN COURT OF APPEALS' DECISION IS STARKLY INCONSISTENT WITH THE FMIA'S PLAIN LANGUAGE AND THIS COURT'S PRECEDENTS 16

TABLE OF CONTENTS — Continued

Page

II. THE DECISION BELOW CREATES CONSIDERABLE UNCERTAINTY ABOUT THE STANDARDS GOVERNING MEAT PRODUCERS AND THREATENS TO DISRUPT THE FEDERAL REGULATORY SYSTEM 22

III. THE DECISION BELOW CLEARLY CONFLICTS WITH DECISIONS OF FEDERAL AND STATE APPELLATE COURTS 26

CONCLUSION 30

TABLE OF AUTHORITIES

Page

Cases:

American Hosp. Ass'n v. *NLRB*,
499 U.S. 606 (1991) 18

American Pub. Health Ass'n v. *Butz*,
511 F.2d 331 (D.C. Cir. 1974) 8, 9, 24, 26

Armour & Co v. *Ball*, 468 F.2d 76
(6th Cir. 1972) 7, 12

Boulahanis v. *Prevo's Family Market, Inc.*,
583 N.W.2d 509 (Mich. Ct. App. 1998) 12, 27

Branch v. *Smith*, 538 U.S. 254,
123 S. Ct. 1429 (2003) 26

CSX Transp., Inc. v. *Easterwood*,
507 U.S. 658 (1993) 22

Cheli v. *Cudahy Bros.*, 255 N.W. 414
(Mich. 1934) 24

Chrysler Corp. v. *Brown*,
441 U.S. 281 (1979) 18

Cipollone v. *Liggett Group, Inc.*,
505 U.S. 502 (1992) 22

Community Nutrition Inst. v. *Block*,
749 F.2d 50 (D.C. Cir. 1984) 17, 30

Cox Broad. Corp. v. *Cohn*,
420 U.S. 469 (1975) 16

Grocery Mfrs. of Am., Inc. v. *Gerace*,
755 F.2d 993 (2d Cir. 1985) 29, 30

Jones v. *Rath Packing Co.*,
430 U.S. 519 (1977) 8

TABLE OF AUTHORITIES — Continued

Page

Kenney v. *Glickman*, 96 F.3d 1118 (8th Cir. 1996) 26

King v. *St. Vincent's Hosp.*, 502 U.S. 215 (1991) 19

Kircos v. *Holiday Food Ctr., Inc.*, 477 N.W.2d 130 (Mich. Ct. App. 1991) 8, 27

Lexecon, Inc. v. *Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998) 19

Meat Trade Inst., Inc. v. *McLaughlin*, 326 N.Y.S.2d 683 (App. Div. 1971) 8

Medtronic, Inc. v. *Lohr*, 518 U.S. 470 (1996) 14

Mourning v. *Family Publ'ns Serv., Inc.*, 411 U.S. 356 (1973) 18

National Pork Producers Council v. *Bergland*, 631 F.2d 1353 (8th Cir. 1980) 29, 30

Public Citizen v. *Foreman*, 631 F.2d 969 (D.C. Cir. 1980) 29, 30

SEC v. *Jerry T. O'Brien, Inc.*, 467 U.S. 735 (1984) 18

Sprietsma v. *Mercury Marine*, 537 U.S. 51 (2002) ... 27, 28

Sullivan v. *Finkelstein*, 496 U.S. 617 (1990) 26

Texas Food Indus. Ass'n v. *Espy*, 870 F. Supp. 143 (W.D. Tex. 1994) 10

Thorpe v. *Housing Auth.*, 393 U.S. 268 (1969) 18

United States Nat'l Bank of Oregon v. *Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439 (1993) 19

TABLE OF AUTHORITIES — Continued

Page

United States v. *Heirs of Boisdore*, 49 U.S. (8 How.) 113 (1849) 19

United States v. *Mead*, 533 U.S. 218 (2001) 19

W.B. Wood Mfg. Co. v. *United States*, 286 F. 84 (7th Cir. 1923) 17

Statutes and Regulations:

21 U.S.C. §§ 451-471 25

21 U.S.C. § 451 26

21 U.S.C. § 452 26

21 U.S.C. § 453 26

21 U.S.C. § 467 26

21 U.S.C. §§ 601-695 ..... *passim*

21 U.S.C. § 601(m) 4

21 U.S.C. § 601(m)(1) ..... *passim*

21 U.S.C. § 601(m)(2) 4, 20

21 U.S.C. § 601(m)(2)(A) 13, 19, 25

21 U.S.C. § 601(m)(3) 13, 17, 20

21 U.S.C. § 601(m)(4) 13, 17, 20

21 U.S.C. § 601(m)(5) 20

21 U.S.C. § 601(m)(6) 20

21 U.S.C. § 601(m)(7) 20

21 U.S.C. § 601(m)(8) 17, 20

21 U.S.C. § 601(n) 24, 25

TABLE OF AUTHORITIES — Continued

	Page
21 U.S.C. § 602	*passim*
21 U.S.C. § 603	4, 5
21 U.S.C. § 604	4, 5, 22
21 U.S.C. § 605	4, 5
21 U.S.C. § 606	4, 5, 22
21 U.S.C. § 607	4, 5
21 U.S.C. § 608	4, 5, 22
21 U.S.C. § 609	4
21 U.S.C. § 610	I, 4, 5, 6, 18
21 U.S.C. § 612	4
21 U.S.C. § 613	4
21 U.S.C. § 615	4
21 U.S.C. § 621	2, 6, 18
21 U.S.C. § 671	5, 6, 18
21 U.S.C. § 672	5, 6, 18
21 U.S.C. § 673	5, 6, 18
21 U.S.C. § 674	5, 6, 18
21 U.S.C. § 675	5, 6, 18
21 U.S.C. § 676	5, 6, 18
21 U.S.C. § 677	18
21 U.S.C. § 678	*passim*
28 U.S.C. § 1257	1, 16

TABLE OF AUTHORITIES — Continued

	Page
7 C.F.R. § 2.53	5
9 C.F.R. § 307.1	5
9 C.F.R. § 307.2	5
9 C.F.R. § 307.3	5
9 C.F.R. § 307.5	5
9 C.F.R. § 307.5	5
9 C.F.R. § 310.1	5
9 C.F.R. § 310.18	10
9 C.F.R. pt. 311	18, 25
9 C.F.R. pt. 316	25
9 C.F.R. pt. 317	25
9 C.F.R. § 317.2	9, 20
9 C.F.R. pt. 319	25
9 C.F.R. § 416.2	5
9 C.F.R. § 416.3	5
9 C.F.R. § 416.4	5
9 C.F.R. § 416.5	5
9 C.F.R. § 416.6	5
9 C.F.R. § 417.2	6
9 C.F.R. § 417.3	6
9 C.F.R. § 417.6	6
9 C.F.R. § 417.8	6, 7

TABLE OF AUTHORITIES — Continued

Page

9 C.F.R. § 500.1 6

9 C.F.R. § 500.2 6

9 C.F.R. § 500.3 6

59 Fed. Reg. 14,528 (Mar. 28, 1994) (codified at 9 C.F.R. § 317.2(l)) 9

60 Fed. Reg. 6774 (Feb. 3, 1995) ..... *passim*

61 Fed. Reg. 38,806 (July 25, 1996) 5, 11

63 Fed. Reg. 11,104 (Mar. 6, 1998) 6

64 Fed. Reg. 2803 (Jan. 19, 1999) ..... *passim*

67 Fed. Reg. 62,325 (Oct. 7, 2002) 10, 20, 28

Miscellaneous:

FSIS Directive 6420.1 (Dec. 17, 1998), *available at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/6420-1.pdf 10

Food Safety and Government Regulation of Coliform Bacteria: Hearing Before the Subcomm. on Agric. Research, Conservation, Forestry, and Gen'l Legis. of the Senate Comm. on Agric., Nutrition, and Forestry, 103rd Cong. 33 (1993) 8, 9

PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the Wisconsin Court of Appeals (App., *infra*, 1a) is reported at 665 N.W.2d 417. The opinion of the Milwaukee County Circuit Court (App., *infra*, 48a) is unreported.

JURISDICTION

The judgment of the Court of Appeals of Wisconsin was entered on May 13, 2003. Petitioner filed a timely petition for review in the Supreme Court of Wisconsin on June 12, 2003. The petition was denied on September 12, 2003. App., *infra*, 44a. The jurisdiction of this Court rests on 28 U.S.C. § 1257(a).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Federal Meat Inspection Act, 21 U.S.C. §§ 601-695, are reproduced in the appendix to this petition at 55a-60a.

STATEMENT

Congress enacted the Federal Meat Inspection Act ("FMIA" or "Act"), 21 U.S.C. §§ 601-695, in order to protect and promote national markets for "wholesome, not adulterated, and properly labeled and packaged meat," and thereby to ensure that meat entering commerce is fit for human consumption. 21 U.S.C. § 602. The Act expressly preempts state requirements "in addition to, or different than" those issued by the Secretary of Agriculture, allowing the States to exercise "concurrent jurisdiction" only with respect to meat that is "adulterated" and therefore unlawful to ship in commerce. *Id.* § 678. The extensive federal regulatory regime — and the area of exclusive federal authority — thus turn upon the distinction between "adulterated" and "unadulterated" meat.

Exercising her general rulemaking authority under the FMIA, the Secretary determined that *intact* meats, such as steaks or roasts, are not "adulterated" if they bear *E. coli* O157:H7 ("*E. coli*") bacteria on their surface, and that these meats may therefore be shipped and sold in commerce, because the bacteria are rendered harmless with ordinary cooking. By contrast, the Secretary has declared *E. coli* to be an adulterant in *ground* meat because it can be more difficult to kill the bacteria that the grinding process may introduce into the meat's interior.

The plaintiffs in these consolidated tort actions became ill after eating items from a salad bar that, according to the Wisconsin Department of Health, had been contaminated with *E. coli* when food was mishandled by a restaurant where plaintiffs dined. They seek to hold petitioner liable for having produced and shipped raw, intact meat that ultimately was resold to the restaurant, alleging that this meat was the original source of the *E. coli* bacteria. The trial court dismissed those claims, finding them to be barred by the FMIA's express preemption provision, while allowing plaintiffs to proceed against the restaurant and its franchisor based upon the mishandling of the food.

The Wisconsin Court of Appeals reversed the dismissal. Concluding that the Secretary of Agriculture lacks authority under the FMIA to interpret the statutory term "adulterated" — notwithstanding the FMIA's express grant of general rulemaking authority (21 U.S.C. § 621) — the court deemed irrelevant the Secretary's determinations regarding whether and when *E. coli* presents a health risk that might render it an adulterant. The court adopted its own interpretation of the term "adulterated," branding any meat product, intact or otherwise, as "adulterated" if it bears even the slightest trace of *E. coli* — *whether or not proper handling and cooking would negate any health risks for those who consume the meat.* The court then

reasoned that, because the FMIA prohibits the sale of "adulterated" meat, tort liability for the sale of such meat is not a preempted additional or different state law requirement but instead falls within the scope of Wisconsin's "concurrent jurisdiction" under the Act. 21 U.S.C. § 678.

The court's decision stripping the Secretary of the general rulemaking authority conferred on her by the FMIA, declining to consider her determinations about when meat is potentially injurious to health, and substituting the court's mechanical and illogical view of the meaning of "adulterated" cannot be reconciled with the plain language of the FMIA or this Court's precedents. Moreover, it conflicts with decisions of several other appellate courts.

Most importantly, the decision below significantly undermines an important regulatory system. It undercuts the Secretary's authority to determine when and how to protect consumers, destroys the national uniformity that Congress mandated and creates intolerable uncertainty for meat processors — who may face criminal and civil liability for processing meat in reliance on USDA standards if, as in this case, courts are free to deem the Secretary's determinations irrelevant and to impose their own idiosyncratic interpretations of the Act. Review of the Wisconsin Court of Appeals' decision is therefore clearly warranted.

A. The Federal Meat Inspection Act

1. *The Regulatory System.* Congress found that uniform federal regulation of meat is necessary both to protect and to promote national markets for "wholesome, not adulterated, and properly labeled and packaged meat," and thereby to prevent "sundry losses to livestock producers and processors of meat" as well as injuries to consumers. 21 U.S.C. § 602. Accordingly, it enacted the FMIA, "establish[ing] sanitary standards for slaughter and processing establishments, and

mandat[ing] antemortem inspection of animals * * * and postmortem inspection of every carcass," as well as requiring continuing inspection of each meat item until it is packaged and sealed for shipment. 60 Fed. Reg. 6774, 6775 (Feb. 3, 1995). *See generally* 21 U.S.C. §§ 603-610, 612-613, 615. All of these requirements are designed to ensure that meat products distributed in commerce are "wholesome, not adulterated, and properly marked, labeled, and packaged." *Id.* § 602.

The Act contains a detailed definition of "adulterated" — the statutory term at the center of this case — that includes both specific elements and more general ones (*see* 21 U.S.C. § 601(m)). Generally, meat is adulterated

> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health; [or]
>
> (2)(A) if it bears or contains * * * any added poisonous or added deleterious substance * * * which may, in the judgment of the Secretary, make such article unfit for human food * * *.

Id. § 601(m)(1)-(2)(A).

The statute aims to prevent the shipment in commerce of "adulterated" meat through two means: an extraordinarily comprehensive federal inspection program and the imposition of civil and criminal penalties on any person who places adulterated meat into commerce.

First, the FMIA authorizes the Secretary to "prescribe the rules and regulations of sanitation under which [meat processing] establishments shall be maintained" (21 U.S.C.

§ 608) and requires government inspection of every such establishment, every carcass, and every meat product (*id.* §§ 603-607). Accordingly, the Food Safety and Inspection Service ("FSIS") of the Department of Agriculture[1] stations federal inspectors in every "official establishment" that slaughters and processes meats for shipment in commerce in order to ensure that the meats produced there are wholesome, unadulterated, and therefore fit for human consumption. 60 Fed. Reg. at 6775.

FSIS inspectors work shoulder-to-shoulder with plant employees and directly supervise every facet of the meat production process, including, among other things, approving plant construction and maintenance, equipment, hours of operation, employee hygiene, manufacturing processes, and speed of production lines. *See, e.g.*, 9 C.F.R. §§ 307.1-.5, 310.1, 416.2-.6; 61 Fed. Reg. 38,806, 38,855 (July 25, 1996). FSIS inspectors also perform an "organoleptic" examination (*i.e.*, one employing the senses of sight, touch, and smell) on *every* live animal before slaughter and *every* carcass after slaughter to screen out diseased animals; and they carefully monitor slaughtering and processing facilities, and every meat product passing through them, to ensure proper sanitation and to prevent the use of dangerous preservatives. 60 Fed. Reg. at 6775-77.

When plant conditions "are such that the meat or meat food products are rendered adulterated," the Secretary "shall refuse" to label meat as having passed federal inspection. 21 U.S.C. § 608. The statute prohibits the shipment and sale of any meats that fail federal inspection (*id.* § 610), and authorizes the Secretary to bring civil and criminal actions for violations of the Act or USDA regulations (*id.* §§ 671-676 (authorizing

---

[1] The Secretary has delegated her statutory authority to the FSIS. *See* 7 C.F.R. § 2.53(a)(2)(ii).

withdrawal of inspection; administrative detention, seizure, and condemnation of adulterated or misbranded meats; actions for injunctive relief; and other civil and criminal penalties)). If a plant produces adulterated meat, the FSIS inspectors may act immediately and without notice to require corrective action or to withhold or suspend federal inspection — thus shutting down the facility. *See* 9 C.F.R. § 500.1-.3.

Second, wholly apart from the inspection requirement, the Act bars any person from selling or transporting "adulterated or misbranded" meat. 21 U.S.C. § 610(c)(1). It also prescribes both civil and criminal penalties for violations. *Id.* §§ 671-676.

Like many federal statutes, the Act endows the Secretary with broad authority to "make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter * * *." 21 U.S.C. § 621; *see also ibid.* (authorizing the Secretary to perform the duties "provided by this chapter and by the rules and regulations to be prescribed by said Secretary").

In the 1990s, FSIS exercised this rulemaking authority to require each federally-inspected facility to conduct a "hazard analysis" to "determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards." 9 C.F.R. § 417.2(a). Each facility must prepare a written Hazard Analysis and Critical Control Point ("HACCP") plan for approval by FSIS. *Id.* §§ 417.2-.3, 417.8.

The purpose of the plan is to further the goal of the federal Act — to "control food safety hazards and prevent the distribution of adulterated livestock products." 63 Fed. Reg. 11,104, 11,105 (Mar. 6, 1998); *see also* 9 C.F.R. § 417.6(e).

Once the agency approves a plan, it applies with the same force as all other USDA regulations, and FSIS verifies and

enforces compliance as part of its ongoing regulatory oversight of the facility. 9 C.F.R. § 417.8. HAACP thus added a new layer of mandatory federal regulation on top of FSIS's long-standing programs of organoleptic inspections and sanitation regulations. All three regulatory approaches are focused on the same goal — preventing distribution in commerce of adulterated meat.

2. *Preemption of State Law.* The FMIA also includes an express preemption clause prohibiting the States from imposing "[r]equirements * * * with respect to premises, facilities and operations of any establishment at which [federal] inspection is provided" that are "in addition to, or different than, those made under [the federal Act]." 21 U.S.C. § 678. This preemption clause also provides, however, that the States "may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected * * * for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of [a slaughtering or processing] establishment." *Ibid.*

Section 678 thus bars States from imposing their own requirements on meat production or processing, or on any aspect of the operation of a federally-inspected facility where such operations take place. However, meats shipped out of such a facility in an "adulterated" or "misbranded" condition are subject to state as well as federal law. States are free, for example, to impose civil and criminal penalties for the sale, distribution, or transportation of "adulterated" and "misbranded" meats; to condemn such meats; and to permit tort liability for injuries resulting from the consumption of such meats. *See, e.g., Armour & Co.* v. *Ball*, 468 F.2d 76, 84 (6th Cir. 1972) (states have authority under 21 U.S.C. § 678 to engage in "concurrent enforcement" with respect to adulterated or misbranded meats, but may not "prevent the distribution in

commerce of any article that 'conforms' to" USDA standards); *Kircos* v. *Holiday Food Ctr., Inc.*, 477 N.W.2d 130, 132 (Mich. Ct. App. 1991) (Michigan has "concurrent jurisdiction for the purposes of preventing the distribution of 'adulterated' food" but is preempted from imposing tort liability for meat not "adulterated" under USDA regulations); *Meat Trade Inst., Inc.* v. *McLaughlin*, 326 N.Y.S.2d 683, 685 (App. Div. 1971) (same); *see also Jones* v. *Rath Packing Co.*, 430 U.S. 519, 529-32 & n.18 (1977) (California may impose statistical sampling to enforce FMIA's net-weight labeling requirements, but only if the state program allows for weight variations permitted by USDA).

B. *E. Coli*-Related Illness And The Federal Response

Bacteria such as *E. coli* and various Salmonella strains naturally "exist in warm-blooded animals." *Food Safety and Government Regulation of Coliform Bacteria: Hearing Before the Subcomm. on Agric. Research, Conservation, Forestry, and Gen. Legis. of the Senate Comm. on Agric., Nutrition, and Forestry* ("*Food Safety Hearing*"), 103rd Cong. 33 (1993) (statement of Mike Espy, Sec'y of Agric.). Many of these bacteria are harmless, but some have the capacity to cause serious illnesses when ingested by humans "depending on the type of microorganism and the immune status of the person infected." 60 Fed. Reg. at 6780.

USDA has repeatedly explained that "proper cooking of meat and poultry products kill[s] harmful bacteria." *Food Safety Hearing*, *supra*, at 122 (statement of Dr. H. Russell Cross, Adm'r, FSIS, before State of Wash. Senate Comm. on Agric., Feb. 2, 1993), App., *infra*, 65a; *see also, e.g.*, 60 Fed. Reg. at 6799 ("proper cooking kills pathogens present on raw [meat]"); *American Pub. Health Ass'n* v. *Butz*, 511 F.2d 331, 332 (D.C. Cir. 1974).

For that reason, prior to 1994 USDA did not consider the presence of any bacteria sufficient to render any raw meat "adulterated." *Food Safety Hearing*, *supra*, at 122 (Cross statement), App., *infra*, 65a ("[meat] products inherently contain bacteria, which does not cause them to be adulterated under law"); *accord Butz*, 511 F.2d at 333.

The agency's approach changed, however, following a much-publicized incident in which several hundred people got sick and four individuals died from eating undercooked hamburgers containing *E. coli* at Jack in the Box restaurants. USDA recognized that this particular strain of bacterium gives rise to special concerns when present in ground beef:

> Ground beef is * * * greatly different from beef roasts and other so-called solid meats. It is potentially a more hazardous product because the grinding process mixes pathogens [*i.e.*, bacteria] normally found only on the surface of solid meats to a relative uniformity throughout the product. This means that adequate cooking must occur throughout the hamburger in order to kill all the pathogens.

Food Safety Hearing, *supra*, at 49 (statement of Dr. Douglas L. Archer, Deputy Dir. for Programs, Ctr. for Food Safety & Applied Nutrition, FDA); *see also* 64 Fed. Reg. 2803, 2803 (Jan. 19, 1999).

Accordingly, in 1994, USDA imposed two new requirements. First, it began mandating labels on all raw meats to warn of the need for proper handling and cooking in order to prevent bacteria-related illnesses. 59 Fed. Reg. 14,528 (Mar. 28, 1994) (codified at 9 C.F.R. § 317.2(l)).

Second, it issued an interpretive rule declaring ground beef to be "adulterated" if it contains *E. coli*, as well as an accompanying procedural rule providing for testing of random

samples of ground beef to determine whether that strain of *E. coli* is present. *See* 67 Fed. Reg. 62,325, 62,326 (Oct. 7, 2002); *Texas Food Indus. Ass'n* v. *Espy*, 870 F. Supp. 143, 145-49 (W.D. Tex. 1994) (denying preliminary injunction to prevent enforcement of interpretive rule that *E. coli* is an adulterant in ground beef).

This rule distinguishes intact meats from ground meat. Because "[i]ntact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7 when consumed," USDA concluded that the presence of *E. coli* (or other bacteria) on the surface of intact meat does not render the meat "adulterated." 64 Fed. Reg. at 2804; *see also* 67 Fed. Reg. at 62,326.

The Secretary developed these rules based upon agency experience and expertise in this area, and has recently reaffirmed their validity in light of extensive data — including results from FSIS's ongoing *E. coli* testing in meat processing facilities, as well as peer-reviewed studies and other scientific evidence issuing from the Centers for Disease Prevention and Control, USDA's Agricultural Research Service, and FSIS's National Advisory Committee on Microbiological Criteria for Foods. *See* 67 Fed. Reg. at 62,325-62,334.[2]

---

[2] The determination that *E. coli* is not an adulterant for intact meat notwithstanding, FSIS still seeks removal of potential sources of pathogens such as visible ingesta and fecal matter (which can be transferred from cattle's digestive tracts or hides to the carcasses) from all meat products, whether they are destined to be served as ground meat or intact cuts. *See* 9 C.F.R. § 310.18. Indeed, during the past decade, the Secretary has moved to a "zero tolerance" system with respect to such identifiable contaminants on meat. *See* FSIS Directive 6420.1 (Dec. 17, 1998), *available at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/6420-1.pdf.

C. Respondents' Lawsuit And The Trial Court's Grant Of Summary Judgment In Favor Of Excel

Petitioner Excel Corporation sold intact cuts of raw sirloin to Sysco Services of Eastern Wisconsin, which in turn resold them to its customer E&B Management Co. Waukesha, Inc., for use as steaks at E&B's Sizzler restaurant franchises in Milwaukee, Wisconsin. *See* App., *infra*, 10a-11a. Before leaving Excel's slaughter and processing facility in Fort Morgan, Colorado, the meat passed USDA inspection to ensure that it was wholesome and not adulterated, and that it therefore could lawfully be shipped and sold for human consumption. *See ibid.* "The meat sold by Excel arrived at the Sizzler restaurant as wrapped intact cuts of beef that bore labels warning the Sizzler employees to cook the meat thoroughly, to keep the raw meat away from other foods, and to wash working surfaces, tools, utensils, and hands after their contact with raw meat." *See id.* at 17a.

In July 2000, the salad bar at E&B's Sizzler franchise became cross-contaminated with *E. coli*. Br. & App. of Def.-Resp't Excel Corp. in Wisconsin Court of Appeals at App. 18. After eating the cross-contaminated food, a number of Sizzler patrons became ill; and a child, Brianna Kriefall, died. The Sizzler patrons brought these common law tort actions in the Circuit Court for Milwaukee County against a variety of

---

While imposing these increasingly rigorous standards with respect to possible sources of bacteria, however, the Secretary has consistently recognized that "[f]ecal contamination * * * does not always correlate with the presence of pathogens." 61 Fed. Reg. at 38,850; *see also* 60 Fed. Reg. at 6780 ("Removing visible fecal contamination is important, but it does not assure the absence of harmful bacteria that cannot be detected visually."). And the Secretary has adhered to her view that intact meat bearing *E. coli* is not adulterated.

defendants, including E&B, Sizzler USA Franchise, Inc. (E&B's franchisor), Sysco (E&B's distributor), Excel, and their respective insurers.

Excel filed a motion for summary judgment, which the trial court granted. App., *infra*, 52a. The court first recognized that Congress has delegated to USDA the authority to "determine when meat is 'safe, wholesome, and not adulterated.'" App., *infra*, 48a-49a (quoting *Ball*, 468 F.2d at 81). The court then reviewed USDA regulations and interpretive rules, and determined that "[i]ntact meat containing surface *E. coli* O157:H7 bacteria is not considered adulterated under federal law because the bacteria is destroyed when the surface of the intact cuts are broiled in establishments like Sizzler's Steak House." *Id.* at 49a (citing 64 Fed. Reg. at 2804).

Relying on *Boulahanis* v. *Prevo's Family Market, Inc.*, 583 N.W.2d 509 (Mich. Ct. App. 1998), which held state tort claims preempted by USDA's pre-1994 decision not to classify *E. coli* as an adulterant in ground beef, the trial court concluded (without making any findings as to whether meat from Excel was the source of the bacteria here) that the plaintiffs' and franchisor's claims against Excel are barred by the FMIA's express preemption clause. App., *infra*, 49a (quoting 21 U.S.C. § 678).

The trial court explained that "[t]he policy behind preemption in this area makes sense." App., *infra*, 49a. It observed that the federal government has established uniform national standards so that properly handled and cooked meat products are safe for human consumption, and so that meat processors know what standards they must satisfy in order to distribute their products. The court concluded that "[t]he federal regulatory scheme * * * preempts any state laws to the contrary. That includes bringing civil suits against meat processors like Excel." *Id.* at 50a.

At the same time, the court noted that federal preemption of the claims against Excel "does not deny these plaintiffs their day in court" because "[t]hey may continue to proceed against the restaurant whose employees handled the food as well as against the restaurant's national franchisor, who is alleged to have improperly trained and supervised it[s] local franchisee." App., *infra*, 50a.

D. The Wisconsin Court Of Appeals' Decision

The Wisconsin Court of Appeals reversed the trial court's grant of summary judgment. App., *infra*, 36a. It held that the Secretary has no statutory authority to interpret the term "adulterated" under the FMIA, and therefore USDA may not prescribe whether or under what circumstances *E. coli* constitutes an adulterant for raw meat.

The court observed that the statutory definition of "adulterated" refers to the Secretary in only one of its nine paragraphs and concluded that the Secretary's interpretative authority was restricted to that one situation: "although Congress has in 21 U.S.C. § 601(m)(2)(A) delegated to the Secretary the responsibility to make a 'judgment' whether 'any . . . added deleterious substance' makes the meat to which the substance is added 'unfit for human food,' Congress has itself, in 21 U.S.C. § 601(m)(1), (3), & (4), defined 'adulterated' without seeking the Secretary's input." App., *infra*, 19a (omission in original).

Thus, reading the statute as prohibiting consideration of the Secretary's views, the court deemed irrelevant USDA's determinations that "'intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products'" and that *E. coli* on the surface of raw intact meat does not render the meat adulterated. *Id.* at 16a (quoting 64 Fed. Reg. at 2804). The court accordingly decided for itself that the presence of *E. coli*

bacteria renders intact meat adulterated under the FMIA. *Id.* at 19a-27a. Because in its view intact meat with *E. coli* on the surface is "adulterated," the court went on to hold that tort liability for the sale of such meat is consistent with the requirements of the FMIA and therefore is not precluded by the Act's express preemption clause. *Id.* at 30a-32a.[3]

The court of appeals also considered whether the tort actions were nonetheless preempted by "the Act's meat-inspection provisions and the regulations promulgated thereunder." App., *infra*, 19a. It held that its conclusion that the meat was "adulterated" within the meaning of the statute precluded preemption on this basis: "a claim premised on damages resulting from the sale of 'adulterated' meat * * * 'merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law.'" *Id.* at 30a (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 495 (1996)). Because, in the court's view, any tort damages would be imposed for conduct violative of federal law, it concluded that the preemption provision does not apply.

---

[3] The court of appeals also stated that Excel was obligated by the HACCP regulations to consider the intended uses of its meat in designing its HACCP plan, and intimated that the meat involved in this case therefore should be classified as non-intact. App., *infra*, 17a-18a. As we have discussed (at pages 6-7, *supra*), however, the HACCP regulations require meat processors to adopt plans to control food safety hazards; they do not constitute the Secretary's construction of "adulterated." The Secretary's interpretation of that term with respect to *E. coli* states that "intact products that are to be distributed for consumption as intact cuts are not deemed adulterated" if they bear *E. coli* bacteria. 64 Fed. Reg. at 2804. The record is clear that the meat products produced by Excel that ended up at the E&B Sizzler restaurant were intact cuts of sirloin. App., *infra*, 10a, 17a. There is no evidence in this case that these intact cuts were converted to ground beef or other non-intact products at the E&B Sizzler, as the trial court found. App., *infra*, 49a.

The Wisconsin Supreme Court denied review without explanation on September 12, 2003. App., *infra*, 44a.

REASONS FOR GRANTING THE PETITION

The Wisconsin Court of Appeals held that it could not even consider the Secretary's views before adopting its own interpretation of the term "adulterated" — an interpretation that runs directly counter to the Secretary's long-standing construction that bacteria are not regarded as adulterants for raw meat if ordinary cooking renders them harmless.

The Wisconsin court's novel conclusions are inconsistent with the plain language of the FMIA and, if permitted to stand, will foster widespread confusion in the industry and among state and federal enforcement personnel about the proper application of the FMIA and the standards for determining whether meat is adulterated. This confusion will significantly undermine the efficacy of our national food-safety system.

Congress's purpose was to create a uniform system of federal regulation — based upon the expert decisions of the Secretary — to prevent the shipment and sale of adulterated meat. But under the approach of the decision below, it is the determinations of the Wisconsin court, not those of the Secretary, that would control the activities of meat processors throughout the Nation. Meat processors seeking to avoid civil and criminal liability could no longer rely upon the Secretary's determinations regarding the meaning of "adulterated" but would have to alter their activities to take account of the differing standards adopted by courts like the one below. Without a clear understanding of what meat is "adulterated," neither the meat industry nor federal and state enforcement personnel will know how to fulfill their legal duties.

It is essential that this Court intervene to assure that the lower state and federal courts give appropriate weight to the

expert determinations of the Secretary and apply the FMIA in the uniform and coherent manner that Congress intended. Review by this Court is plainly warranted.[4]

I. THE WISCONSIN COURT OF APPEALS' DECISION IS STARKLY INCONSISTENT WITH THE FMIA'S PLAIN LANGUAGE AND THIS COURT'S PRECEDENTS.

The judgment below rests entirely on the court of appeals' surprising conclusion that the Secretary of Agriculture has no legal authority to interpret the key statutory term "adulterated." App., *infra*, 19a. Reading the statutory definition of that term as a congressional prohibition against giving any weight to the Secretary's interpretation, the court entirely ignored USDA's determinations about the actual health risks of *E. coli* O157:H7, deciding, contrary to the agency, that the presence of surface *E. coli* renders intact meat "adulterated" under the FMIA. *Id.* at 13a-14a. The court then reversed the trial judge's finding of

---

[4] The lower court's judgment is "[f]inal" within the meaning of 28 U.S.C. § 1257. The federal issue of whether the Secretary of Agriculture has the authority to interpret the statutory term "adulterated," and thus whether common-law tort actions are preempted by the Secretary's determination that the type of meat at issue may lawfully be shipped in commerce, "has been finally decided in the state courts with further proceedings pending in which [Excel] might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court." *Cox Broad. Corp.* v. *Cohn*, 420 U.S. 469, 482 (1975). Moreover, "reversal of the state court on the federal issue would be preclusive of any further litigation" because, in that case, the state-law cause of action against Excel would be preempted. *Id.* at 482-83. And, as we will show below, a "a refusal immediately to review the state court decision might seriously erode [the] federal policy" of establishing and enforcing uniform national standards for wholesomeness and safety of meats shipped in interstate commerce. *Id.* at 483.

federal preemption because the statute does not preempt tort claims with respect to "adulterated" meat. *Id.* at 29a-30a.

Each link in the chain of inferences that the court used to strip the Secretary of her rulemaking authority and adopt its rigid and illogical interpretation of the statute is irreconcilable with the plain language of the FMIA, violates well-settled canons of statutory construction, and defeats the legislative purposes underlying the Act.

1. The term "adulterated" delineates one of the most critical dividing lines established by the FMIA. It separates meat that may be distributed in commerce from meat that may not. And it identifies meat whose distribution may subject meat processors to the States' "concurrent jurisdiction" — including civil and criminal penalties and tort liability.

Yet the statutory definition of "adulterated" itself contains a number of terms that are far from clear. For example, Congress did not endeavor to define the term "injurious to health" in the definition of "adulterated." Nor, for that matter, did it specify what constitutes a "filthy, putrid, or decomposed substance," "insanitary conditions," or removal of a "valuable constituent" — though it generally identified all of these as circumstances rendering meat adulterated. 21 U.S.C. § 601(m)(3), (4), (8). "[T]he relatively unspecific nature of the * * * standard[s] which Congress has prescribed * * *, combined with the evident need for expert and technical judgment in applying [these] standard[s], suggests that this is an area in which courts must give great deference to the Secretary's judgments." *Community Nutrition Inst.* v. *Block*, 749 F.2d 50, 54 (D.C. Cir. 1984) (Scalia, J.); *cf. W.B. Wood Mfg. Co.* v. *United States*, 286 F. 84, 86 (7th Cir. 1923) ("Congress [did] not assume[] to define with absolute particularity what is or what is not injurious" in the FMIA's companion legislation, the Food and Drug Act of 1906, and the

meaning of the statutory term "deleterious ingredient, injurious to health" comes down to "a difference between chemists over the meaning of the words").

It is therefore entirely appropriate — indeed, absolutely necessary — for the Secretary to exercise her general rulemaking authority (21 U.S.C. § 621) to issue rules and regulations defining these terms and clarifying the standards that render meat adulterated if the purposes of the FMIA are to be achieved; and that is just what the Secretary has done. *See, e.g.*, 9 C.F.R. pt. 311. Meat processors simply could not comply with the statutory prohibition against shipping meat that is "adulterated or misbranded" (21 U.S.C. § 610(c)(1)) — on threat of civil and criminal penalties for a violation (*see id.* §§ 671-677) — without such guidance from the Secretary.

The court of appeals' conclusion that Congress intended to deprive the Secretary of any role in interpreting these aspects of the statutory definition of "adulterated," and that the Secretary's view therefore could not be given any weight, simply makes no sense.

This Court has consistently recognized Congress's power to make general delegations of rulemaking authority like the one in Section 621 of the FMIA — irrespective of whether the same statute also includes specific delegations. *See, e.g.*, *American Hosp. Ass'n* v. *NLRB*, 499 U.S. 606, 609-10 (1991); *SEC* v. *Jerry T. O'Brien, Inc.*, 467 U.S. 735, 745 (1984); *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 306 (1979); *Mourning* v. *Family Publ'ns Serv., Inc.*, 411 U.S. 356, 369 (1973); *Thorpe* v. *Housing Auth.*, 393 U.S. 268, 280-81 (1969).

Congress's specific delegation of authority to the Secretary in Subsection 601(m)(1)(2)(A), a single clause of the nine-paragraph statutory definition of "adulterated," cannot reasonably be read to limit this general rulemaking authority. "Over and over [this Court has] stressed that '[i]n expounding

a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'" *United States Nat'l Bank of Oregon* v. *Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (quoting *United States* v. *Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122 (1849)). The Wisconsin Court of Appeals' view that Subsection 601(m)(2)(A)'s reference to the Secretary's "judgment" constitutes a congressional prohibition against administrative rulemaking with respect to any other part of the statutory definition of "adulterated" — and a congressional mandate to disregard entirely the Secretary's expert judgments about what constitutes an adulterant — ignores this "central tenet of interpretation." *Lexecon, Inc.* v. *Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 36 (1998) ("a statute is to be considered in all its parts when construing any one of them"); *accord King* v. *St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991) (it is a "cardinal rule that a statute is to be read as a whole, since the meaning of statutory language, plain or not, depends on context") (citations omitted).[5]

2. Moreover, the Secretary's interpretation of the statute is much more consistent with the language and purpose of the statute than the rigid, illogical construction adopted by the court of appeals.

The FMIA generally defines meat as adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, [the meat] shall not be considered adulterated under this clause if the quantity of such substance in or on

---

[5] Certainly the Wisconsin court was not entitled to ignore the Secretary's interpretation simply because it was embodied in an interpretive rule. Indeed, this Court recently rejected that view in *United States* v. *Mead*, 533 U.S. 218 (2001).

[meat] does not ordinarily render [the meat] injurious to health." *Id.* § 601(m)(1). In other words, the Act identifies meat as "adulterated" or not depending upon whether it will harm the health of those who eat it.

The specific conditions that Congress went on to identify as rendering meat adulterated are all to the same effect. Whether the concern is that the meat bears an "unsafe" pesticide or additive (21 U.S.C. § 601(m)(2)), that it consists of "filthy, putrid, or decomposed" substances (*id.* § 601(m)(3)), that it has been prepared under "insanitary conditions" (*id.* § 601(m)(4)), that it is "the product of an animal which has died otherwise than by slaughter" (*id.* § 601(m)(5)), that it is packed in a container that may impart a poisonous substance (*id.* § 601(m)(6)), that it has been subjected to harmful radiation (*id.* § 601(m)(7)), or that a "valuable constituent" has been removed or an inferior one substituted (*id.* § 601(m)(8)), the whole point of the statutory definition of "adulterated" is to ensure that the meat is fit to eat and not "injurious to health."

Consistent with this legislative purpose, the Secretary has declared *E. coli* to be an adulterant for ground meat and not one for intact meat only after determining, based on her expertise, that if each package is properly labeled to warn of the possibility of bacteria-related illnesses and the attendant need for safe handling (*see* 9 C.F.R. § 317.2(k)-(l)), the presence of surface *E. coli* on raw intact meat creates no health risks for those who eat the meat because the bacteria are killed with ordinary cooking. 67 Fed. Reg. at 62,326; 64 Fed. Reg. at 2804. In other words, the Secretary has concluded that *E. coli* does not "render" properly labeled raw intact meat "injurious to health" (21 U.S.C. § 601(m)(1)), and hence, such meat does not satisfy the statutory definition of "adulterated."

The Wisconsin Court of Appeals's contrary interpretation is so rigid that it simply makes no sense. Although recognizing

that meat bearing *E. coli* "can be rendered non-'injurious to health'" by the simple expedient of cooking it, the court nonetheless reasoned that this fact is irrelevant because Subsection 601(m)(1) defines "adulterated" to include meat bearing any substance that "may" render it injurious to health. App., *infra*, 14a. In the court's view, Congress's use of the word "may" means that any substance that "may" under any circumstance be "injurious to health" is an adulterant — irrespective of what the possible injury to health might be, how unlikely it is to occur, how easily it may be avoided, or what measures USDA or the meat processor might take to ensure that it will not come to pass.

All raw meat contains some bacteria — which is why meat spoils if it is not refrigerated. It therefore bears substances that "may" render it "injurious to health" if it is not properly handled and cooked. On the court of appeals' theory, all raw meat would accordingly be "adulterated" and unlawful to sell, and no federal inspector could ever inspect and pass any carcass as fit for human consumption because there would always be the possibility that it might injure someone's health. Surely that is not what Congress had in mind when it enacted the FMIA.

In sum, the decision below is clearly wrong. It rests on a fundamental misreading of both the plain statutory language and this Court's precedents.[6]

---

[6] The court of appeals did not reach the question whether the FMIA preempts tort claims against processors concerning meat that the Act permits to be distributed in commerce, but the plain language of the statute makes clear that Congress intended for such claims to be preempted. *See* 21 U.S.C. § 678 (prohibiting imposition of any "[r]equirements within the scope of [the Act] * * * which are in addition to, or different than" those imposed by federal law, and affording States concurrent jurisdiction only over the distribution and

II. THE DECISION BELOW CREATES CONSIDERABLE UNCERTAINTY ABOUT THE STANDARDS GOVERNING MEAT PRODUCERS AND THREATENS TO DISRUPT THE FEDERAL REGULATORY SYSTEM.

The decision of the Wisconsin Court of Appeals will have significant repercussions that extend far beyond this case. By eliminating the Secretary's authority to construe key terms of the FMIA such as "adulterated" — and allowing courts, and presumably state regulators, to reach their own conclusions about the meaning of those terms — the decision below replaces the relative certainty and clarity of the current system with an ad hoc regime that, as in this case, would produce competing standards from the Secretary and the States. Meat processors trying to comply with multiple "rules" would be left to navigate the ensuing confusion, potentially subject to criminal and civil penalties as well as tort liability in the event that a court subsequently determined that they erroneously relied upon the Secretary's standards. Similarly, FSIS inspectors in plants across the Nation would no longer have one standard by which to determine which meat should be "inspected and passed" (*see* 21 U.S.C. §§ 604, 606, 608) under the Act.

---

sale of "adulterated or misbranded" meat). If processors were subject to tort liability for unadulterated meat, they would have to modify their procedures in order to avoid that state-law liability — precisely the sort of state-law interference with the federal regime that Congress sought to preclude by enacting broad preemption language. *See CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality op.); *id.* at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part). Not surprisingly, no appellate court other than the court below has permitted the imposition of tort liability in these circumstances.

If the Wisconsin Court of Appeals was correct in holding that it should not even consider USDA's rules, practices, and interpretive decisions, but must instead decide entirely for itself whether and when *E. coli* might be an adulterant — and the State may then impose the court's divergent view through tort liability, civil fines, or even stiff criminal penalties under the guise of enforcing the FMIA — a meat processor such as Excel may have no choice but to adhere to Wisconsin's standard for all of its products that ultimately will be sold or served in the State. But that result would undercut Congress's intent that the Secretary of Agriculture should be the one to make determinations about when meat is legal to ship and sell.

Because the market for meat is a national one (21 U.S.C. § 602), moreover, meat processors typically have no idea where their products will eventually be sold or served. The only way that they can avoid tort liability in Wisconsin — not to mention criminal prosecution in that State for shipping "adulterated" meat — may therefore be to regard the court of appeals' interpretation of the FMIA, and not USDA's, as the national standard and to conform *all* of their products to it.

What is more, other States may try to follow Wisconsin's lead and adopt their own interpretations of the statute based on their own views of the relevant scientific and public-health issues. The possibility of multiple, and potentially conflicting, standards is obvious.

Here, for example, USDA sent a letter to Excel reaffirming its view that intact meat bearing *E. coli* is *not* adulterated. App., *infra*, 62a. Under the court of appeals' decision, however, such meat *is* adulterated and may not lawfully be placed in commerce. If that decision is permitted to stand, Excel will be placed on the horns of a dilemma — follow the Secretary's determination and risk liability under state law, including possibly sanctions from state regulators, or follow the

court's approach and alter the processes at its plants (which would require USDA approval), potentially shifting resources away from the prevention of risks that the Secretary has identified as priorities.

Nor is USDA's *E. coli* rule the only standard implicated by the court of appeals' decision. If the Wisconsin court was correct in concluding that the Secretary lacks authority to determine whether and when *E. coli* is an adulterant, then the same argument might be made for various strains of Salmonella and also for trichinae spiralis — a parasite in fresh pork that causes the potentially-fatal disease trichinosis. Both of these substances are commonly found in raw meat; their potential to cause illness has long been known to consumers; and, like *E. coli* on intact meat, any dangers to health that they may pose are entirely eradicated through normal cooking. *See, e.g.*, 60 Fed. Reg. at 6799-80; *Butz*, 511 F.2d at 332; *Cheli* v. *Cudahy Bros.*, 255 N.W. 414 (Mich. 1934). Yet the Wisconsin court of appeals' interpretation of the statutory term "adulterated" might be viewed as compelling the conclusion that raw meat bearing any trace of Salmonella or trichinae is adulterated.

Moreover, on the Wisconsin court's reasoning, the Secretary of Agriculture would lack rulemaking authority not only with respect to substances such as *E. coli*, Salmonella, and trichinae, but also with regard to all of the other possible adulterants covered by the entire nine-paragraph statutory definition of "adulterated" — with the exception of the narrow range of determinations that Subsection 602(m)(2)(A) specifically commits to the Secretary's "judgment." And the same reasoning might be applied to deny or rigidly limit the Secretary's rulemaking authority under at least eight of the twelve paragraphs of the FMIA's definition of "misbranded." *Compare* 21 U.S.C. § 601(n)(10) (meat purporting to be for "special dietary uses" is "misbranded" unless its label includes information prescribed by the Secretary) *with id.* § 601(n)(1)-

(4), (6) (making no reference to USDA rules or regulations) *and id.* § 601(n)(5), (9), (11) (affording discretion to grant limited exceptions to labeling requirements but not specifically recognizing general rulemaking authority).

Accordingly, the Wisconsin court's decision does not just displace the Secretary's determination regarding when *E. coli* or similar substances constitute adulterants; it effectively nullifies substantial portions of the entire system of federal meat inspection, including the long-standing, carefully-wrought, and highly detailed USDA regulations concerning non-adulteration and proper labeling, branding, and packaging. *See, e.g.*, 9 C.F.R. pt. 311 (diseases and other conditions rendering meat adulterated); *id.* pt. 316 (marking requirements); *id.* pt. 317 (labeling requirements); *id.* pt. 319 (standards of identity and composition).

That means companies like Excel that do business nationwide face an intolerable choice. Either they must comply with federal regulations — as Excel undeniably did here — and run the risk of tort liability, fines, and even prison sentences whenever a court subsequently disagrees with USDA about what constitutes an adulterant or a misleading label — or else they must attempt to predict what future courts might find to constitute adulteration or misbranding — and run the risk of being found in violation of the FMIA for making their products and packaging conform to those courts' preferences. Clearly, that is not what Congress envisioned when it enacted Section 678 of the federal Act.

Even that is not the full extent of the problem, for the Wisconsin Court of Appeals' denial of the Secretary's regulatory authority could be read to undercut laws in addition to the FMIA. The Poultry Products Inspection Act ("Poultry Act"), 21 U.S.C. §§ 451-471, is modeled on the FMIA (*see* 60 Fed. Reg. at 6776) and incorporates almost verbatim the

FMIA's statement of congressional findings (*id.* § 451), its statutory definitions of "adulterated" and "misbranded" (*id.* § 453(g)-(h)), and its express preemption provision (*id.* § 467e). In accordance with the canon of statutory construction that "statutes *in pari materia* should be interpreted harmoniously" (*Sullivan* v. *Finkelstein*, 496 U.S. 617, 632 (1990) (Scalia, J., concurring in part); *see also Branch* v. *Smith*, 538 U.S. 254, 123 S. Ct. 1429, 1446 (2003)), the lower courts have already recognized that the FMIA and the Poultry Act should presumptively be interpreted the same way. *See, e.g.*, *Kenney v. Glickman*, 96 F.3d 1118, 1124-25 (8th Cir. 1996); *Butz*, 511 F.2d at 334-35. The Wisconsin court's decision thus threatens the Secretary's rulemaking authority under the Poultry Act, thereby defeating Congressional intent to create a uniform national system for preventing the shipment and sale of adulterated and misbranded poultry. *See* 21 U.S.C. §§ 451-452, 467(e).

This Court should grant review to prevent the significant disruption of our national food-safety system that is an inevitable consequence of the court of appeals' ruling.

III. THE DECISION BELOW CLEARLY CONFLICTS WITH DECISIONS OF FEDERAL AND STATE APPELLATE COURTS.

The decision below creates several clear conflicts among the state and federal appellate courts with respect to important provisions of the FMIA. Congress specifically emphasized the need for national uniformity when it enacted this statute (*see* pages 3-4, *supra*); but the decision below imposes conflicting standards governing whether particular types of meat are "adulterated" — and therefore subjects meat processors to inconsistent obligations — depending upon where their product ends up being sold or served. This Court should grant review

to preserve the federally-regulated national market that Congress intended to create when it enacted the FMIA.

To begin with, the decision of the Wisconsin Court of Appeals squarely conflicts with *Boulahanis* v. *Prevo's Family Market, Inc.*, *supra*. In *Boulahanis*, the Michigan Court of Appeals held that the FMIA preempted claims arising out of pre-1994 sales of ground beef containing *E. coli*. 583 N.W.2d at 511-12. The court concluded that the Secretary's judgment at that time (that *E. coli* was not an adulterant in ground beef) constituted an "intentional decision not to regulate the presence of E. Coli * * * [that] carries the force of a positive enactment." *Id.* at 512. Accordingly, the court reasoned that the plaintiffs' common-law tort actions were preempted by federal law because "[h]olding defendants liable for failing to detect the presence of E. Coli bacteria in the meat purchased by plaintiffs in 1993 would run contrary to the USDA's then-existing determination that inspection for E. Coli bacteria was not required." *Ibid.*

Boulahanis is consistent, moreover, with the Michigan Court of Appeals' prior ruling in *Kircos* v. *Holiday Food Center, Inc.*, 477 N.W.2d 130 (Mich. Ct. App. 1991), which held that the FMIA preempts common-law tort claims by consumers who contract trichinosis after eating federally-inspected pork. *Id.* at 132-33 (state-law claims preempted because Secretary has not identified trichinae as an adulterant in fresh pork).

The trial court explicitly relied on *Boulahanis* in dismissing this action. App., *infra*, 49a. The Wisconsin Court of Appeals attempted to distinguish *Boulahanis* on two grounds. First, it noted this Court's explanation in *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002), that agency inaction might evidence *either* a federal mandate to leave the area unregulated *or* "'an intent to preserve state regulatory authority pending the adoption of

specific federal standards.'" App., *infra*, 34a-35a (quoting *Sprietsma*, 537 U.S. at 65). But that discussion in *Sprietsma* concerns a claim of *implied* preemption. 537 U.S. at 65-66. The instant case, by contrast, falls squarely within the FMIA's *express* preemption clause. Congress clearly expressed its intent to vest the Secretary with exclusive regulatory authority in this area, limiting the States' "concurrent jurisdiction" to "adulterated" meat; if the Secretary declares a type of meat to be unadulterated and fit for human consumption, the States are not free to impose a contrary requirement. There is no reason whatever to believe that *Sprietsma* would alter the Michigan court's view of express preemption under the FMIA.

Second, the Wisconsin court pointed to the fact that, "contrary to the situation in *Boulahanis*, the [FSIS] is now not only concerned with E. coli O157:H7, but, indeed, is striving to reduce its presence in meat * * *." App., *infra*, 35a. The Secretary's active regulation in this area — and her explicit distinction between intact meat and ground meat (*see* 67 Fed. Reg. at 62,326) — only underscores that conflicting or additional state requirements, such as common-law tort liability for shipping types of meat that the Secretary has deemed to be unadulterated, would interfere with Congress's plan to protect producers, consumers, and national markets through a uniform system of federal regulation grounded on the Secretary's expertise.

The declaration by the court below that *Boulahanis* is "irrelevant" is unsupported by any valid legal or factual distinction, and rests on nothing more than the Wisconsin Court of Appeals' disagreement with the Michigan Court of Appeals. That is a disagreement that should be resolved by this Court.

The decision of the Wisconsin Court of Appeals also conflicts with decisions of the Second, Eighth, and D.C. Circuits holding that the Secretary has broad rulemaking

authority under the FMIA and that courts cannot, therefore, dismiss her views out of hand. *See Grocery Mfrs. of Am., Inc.* v. *Gerace*, 755 F.2d 993, 1001-02 (2d Cir. 1985); *National Pork Producers Council* v. *Bergland*, 631 F.2d 1353, 1361-62 (8th Cir. 1980); *Public Citizen* v. *Foreman*, 631 F.2d 969, 975 (D.C. Cir. 1980).

In *Gerace*, the Second Circuit upheld a USDA interpretation of the statutory term "imitation" for purposes of the FMIA's labeling requirements. Although noting that it was "not bound by interpretive rules," the court concluded that "USDA's longstanding interpretation of the FMIA * * * branding provisions" was "a reasonable interpretation and therefore entitled to judicial respect." 755 F.2d at 1001-02 (citation omitted). In *Foreman*, the D.C. Circuit upheld the validity of a USDA regulation concerning the use of nitrites in cured meats despite a consumer group's allegation that those preservatives are "unsafe," explaining that "courts appropriately accord substantial deference to agencies' interpretations of the regulations they must administer, and that such deference is especially prudent in areas involving scientific and medical controversies." 631 F.2d at 975 (citations omitted). And, more generally, the Eighth Circuit recognized in *Bergland* that "the statutory grant of authority to the Secretary is broad, and no restrictions on the permissible types of standards are contained in the [FMIA]." 631 F.2d at 1362. Thus, as long as the Secretary's regulations "bear[] a rational relationship" to her congressionally-mandated duty to ensure that meat products are "'wholesome, not adulterated, and properly marked, labeled, and packaged,'" the court concluded that they are legitimate exercises of agency authority. *Id.* at 1361.

Whether or when meat bearing *E. coli* is "injurious to health" (21 U.S.C. § 601(m)(1)) is surely the sort of "scientific and medical controvers[y]" that cries out for expert agency

judgment. *Foreman*, 631 F.2d at 975; *cf. Community Nutrition*, 749 F.2d at 54 (need for "expert and technical judgment" in applying nonspecific statutory standards "suggests that this is an area in which courts must give great deference to the Secretary's judgments"). The Wisconsin Court of Appeals' determination that Congress barred it from even considering the Secretary's views on the meaning of "adulterated" is thus entirely at odds with the decisions in *Bergland*, *Foreman*, and *Gerace*.

* * *

In sum, the decision of the Wisconsin Court of Appeals undermines the central purposes of the FMIA, calls into question the broader regulatory powers of the Secretary of Agriculture, and conflicts with the decisions of other state and federal appellate courts. This Court should grant *certiorari*, reverse the judgment below, and thereby prevent the Wisconsin court from usurping federal rulemaking authority and disrupting a critically important federal regulatory program.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

RALPH A. WEBER
AMELIA L. MCCARTHY
SHAWN K. STEVENS
Reinhart Boerner Van Deuren S.C.
1000 North Water Street
P.O. Box 2965
Milwaukee, WI 53201
(414) 298-1000

ANDREW J. PINCUS
Counsel of Record
RICHARD B. KATSKEE
Mayer, Brown, Rowe & Maw LLP
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

DECEMBER 2003